

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 4-66								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-08-010	Contract Period 12/16/2008 To 05/30/2014 Base                      Option Period Number    4	Title of Work Assignment/SF Site Name External Peer Review of the fo								
Contractor SCIENTIFIC CONSULTING GROUP, INC, THE		Specify Section and paragraph of Contract SOW 2.2, 2.3								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance  From 12/01/2012 To 05/30/2014								
Comments: External Peer Review of the following draft risk assessments: Antimony Trioxide (CASRN 1309-64-4) and HHCB (CASRN 1222-05-5)										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data		<input checked="" type="checkbox"/> Non-Superfund								
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 12/16/2008 To 05/30/2014		Cost/Fee:		LOE:						
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name David Brooks							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number 202-564-8603			
							FAX Number:			
Project Officer Name Melissa Revely-Wilson							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 703-347-8523			
							FAX Number: 703-347-8696			
Other Agency Official Name							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number:			
							FAX Number:			
Contracting Official Name Camille W. Davis							Branch/Mail Code:			
_____ (Signature)                      (Date)							Phone Number: 513-487-2095			
							FAX Number: 513-487-2115			



## **PERFORMANCE WORK STATEMENT**

**Contract Number: EP-C-08-010**

**Work Assignment Number 04-66 Extension**

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**Title:** Title: External External Peer Review of the following draft risk assessments: Antimony Trioxide (CASRN 1309-64-4), HHCB (CASRN 1222-05-5), and Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4).

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**SOW Section & Paragraph:** 2.2, 2.3

**PERIOD OF PERFORMANCE:** Option Year 4 Extension: December 1, 2013 contract period of performance.

### **I. Background**

As part of EPA's continuing comprehensive approach to enhance the Agency's existing chemicals management program, in March 2012, EPA identified a work plan of 83 chemicals for further assessment under the Toxic Substances Control Act (TSCA). EPA identified seven of these chemicals for risk assessment in 2012. EPA intends to use the TSCA Work Plan Chemicals to help focus and direct the activities of the Existing Chemicals Program over the next several years. The documents to be reviewed consist of a Risk Assessment (approximately 100 pages in length plus 150 pages of references and appendices).

### **II. OBJECTIVE**

The U.S. EPA's Office of Pollution Prevention and Toxics (OPPT) has a requirement for external peer reviews of four documents: 1) Antimony Trioxide (CASRN 1309-64-4); 2) HHCB (CASRN 1222-05-5); and 3) Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4), that the accuracy, content, and interpretation of findings be factual and scientifically sound. The review shall generate comments from the individual expert reviewers.

### **III. DESCRIPTION OF TASKS**

The contractor shall conduct the following tasks to accomplish the objective of this project: a) identify and select peer reviewers with appropriate expertise and determine absence of conflict of interest; b) provide the charge and review package contents to the reviewers; c) establish schedules and coordinate logistics for the letter peer review; and d) receive and compile written peer reviewer comments.

All work to be done under this work assignment shall be in compliance with the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006).

The documents to be reviewed consist of a Risk Assessment (approximately 100 pages in length plus 150 pages of references and appendices).

A) Task 1 - Identify Scientific and Technical Experts for 1) Antimony Trioxide (CASRN 1309-64-4) and 2) HHCB (CASRN 1222-05-5)

EPA is soliciting nominations of expert peer reviewers via a FRN from the public and submission of names with contact information (full name, address, affiliation, phone and e-mail) should be made within 30 days of the opening of this public comment period. The nominations of expert peer reviewers from the public will be relayed to the independent peer review contractor setting up the individual peer review panels.

Antimony Trioxide (CASRN 1309-64-4): The contractor shall independently identify a pool of 14 potential reviewers from which the contractor shall select and secure arrangements with 7 reviewers who are experts in the following areas: exposure modeling expert, aquatic ecotoxicology, terrestrial ecotoxicology, and inorganic chemist addressing water and sediment issues, and ground water. Experts shall be chosen by the contractor to participate in the external peer review panel. While contractor shall choose experts based upon scientific expertise, the contractor is encouraged to consider experts with diverse backgrounds that represent a range of employment sectors.

HHCB (CASRN 1222-05-5): The contractor shall independently identify a pool of 14 potential reviewers from which the contractor shall select and secure arrangements with 7 reviewers who are experts in the following areas: aquatic ecotoxicology, terrestrial ecotoxicology, fate and biodegradation, fate and bioaccumulation, environmental risk assessment (aquatic and terrestrial), analytical chemistry of organic waste water contaminants and human health risk assessment. Experts shall be chosen by the contractor to participate in the external peer review panel. While contractor shall choose experts based upon scientific expertise, the contractor is encouraged to consider experts with diverse backgrounds that represent a range of employment sectors.

The contractor shall certify in writing to the WAM that the selected reviewers are free from any conflict of interest or an appearance of a lack of impartiality as follows:

1. Within 1 week of the initial conference call (via letter to EPA, see template for the selection of peer reviewers' letter);
2. Two weeks before the meeting (notice of recertification); and
3. The day of the meeting (notice of recertification).

The contractor shall instruct peer reviewers to report any changes that would impact their COI or impartiality status anytime during the process. The contractor shall immediately notify the CO, the PO and WAM of any changes.

All of the reviewers shall also have broad expertise in the area of toxicology, and understanding of EPA risk assessment guidance. The reviewers shall have scientific credentials equivalent to a Ph.D. or M.D. and shall be regarded as experts in their field. Expertise shall be judged by authorship on original publications and/or reviews in peer-reviewed scientific journals. Reviewers may also be judged by other measures of expertise including professional accomplishments and recognition by professional societies.

The contractor shall provide the WAM with the affiliation, qualifications, and curriculum vitae for each of the 10-14 candidate reviewers. The contractor shall ensure that the candidate reviewers meet the technical selection criteria and determine any actual or potential conflict of interest where it exists. Contractor will ask the potentially qualified candidates if they are interested and available for the date(s) of the peer review meeting(s). From each person that is interested and available, the Contractor will obtain: (a) a current, complete resume, (b) a completed conflict of interest form containing the information specified by EPA, and (c) if not on the resume, a list of pertinent publications during the past 5 years, with identification of the funding source(s) for the work presented in each publication. The Contractor will supplement the information from candidates by Internet searches and other methods that are appropriate. If EPA determines that the reviewers are scientifically unqualified for the specific review, the contractor shall have five days to submit substitutes for review. The

WAM can provide comments to the contractor regarding the expertise and potential conflicts of interest of the proposed reviewers. The final selection of reviewers will be the responsibility of the contractor. The contractor shall designate one of the reviewers as the Panel Chair with the approval of the WAM. This individual shall have demonstrated abilities for leading a scientific group and shall have a working knowledge of EPA risk assessment practices.

The contractor shall contact the approved candidates and arrange for their participation in the review and attend 3 conference/web conferences calls, tentatively scheduled to begin spring 2013. Review materials will include the charge to the reviewers and a Draft External Peer review Draft Risk Assessment with electronic copies of references cited and/or access to the health & Environmental Research Online (HERO) database <http://hero.epa.gov/> (all provided by the EPA WAM). A draft charge will be provided to the contractor containing questions identified by the Agency. These charge questions must be included in the final charge. The contractor may add questions or suggest revisions to the charge provided by EPA. The charge must be consistent with the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006).

Information collected and maintained by Contractors from nominators of peer review candidates, or from the peer review candidates themselves, may be subject to the Privacy Act (PA). The PA requires agencies to publish a system of records notice (SORN) in the Federal Register if they maintain records that contain information about an individual and the records are retrieved by a personal identifier, such as a name, social security number, email address, mailing address, etc. The PA is not limited to records in EPA's possession. The PA contains a provision that says that if an agency uses a Contractor to operate a system of records by or on behalf of the agency to accomplish an agency function, the agency shall apply the PA to that system. Contractors and their employees who operate systems of records by or on behalf of an agency are also subject to criminal penalties under the PA, as if they were agency employees (5 U.S.C. 552a(m)(1)). EPA has not established a SORN to cover information that Contractors might obtain about nominators of peer review candidates or peer review candidates. Accordingly, Contractors should not manage any contract-related records containing personal information about individuals in such a way that the information is retrieved by a personal identifier. Questions about the PA and its applicability should be directed to the contracting officer.

Deliverable 1. The Contractor shall provide a COI certification letter of the decision that includes a list of (14) prospective reviewers within 1 week of the initial conference call. The letter shall certify that either no COI or appearance of a lack of impartiality exists or such has been resolved for each prospective reviewer.

Deliverable 1A: CVs for the peer reviewers	Due: Two weeks after WA award
Deliverable 1B: Draft expert panel selection	Due: Three weeks after WA award

C. Task 2 -- Pre-Meeting Review Period and Comments for Antimony Trioxide (CASRN 1309-64-4), HHCB (CASRN 1222-05-5), and Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4).

The contractor shall draft instructions to the reviewers in accordance with the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006). The instructions shall inform the reviewers that their pre-meeting and post-meeting written comments will be made publicly available via distribution at the peer review meeting and the OPPT web site via links to the e-docket, respectively. The instructions shall also inform reviewers that from the time they accept the invitation to review the assessment; they should have no communications with members of the public, EPA, or other federal agencies on the assessment under review.

Reviewers shall be instructed that if they are contacted in person or in writing on the assessment by anyone other than the contractor or another panel member, they should immediately inform the contractor. The contractor shall immediately inform the PO and WAM of any reports by panel members of pre-meeting contacts regarding the assessment under review.

The contractor shall provide and send to each reviewer the Draft Workplan Risk Assessment, the charge to the reviewers, and instructions for the peer review according to the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006).

The contractor shall manage and monitor the review process and deliverable due dates. The reviewers will be allowed 6 weeks to complete their initial review. The contractor shall receive and compile reviewers' comments in a draft pre-meeting document. The contractor shall review the comments to ensure that the reviewers have fulfilled their responsibilities under their agreement with the contractor. The contractor is not to edit nor rearrange comments, but provide them in an electronic format (MS Word 2007 format or higher), as they are sent in the original form with reviewers' cover/comment letter. The compiled comments shall be provided to the WAM at least 10 days before the peer review panel meeting. An electronic copy of the draft final pre-meeting document shall be provided to each reviewer at least 10 days before the peer review panel meeting.

At least 90 days prior to the date of the first meeting, EPA will announce in the Federal Register: (a) the availability of the assessment to the public, including a request for public comment (60 day public comment period);

At least 60 days prior to the first meeting The Contractor will select a proposed final review panel based on: (a) expertise, knowledge and experience of each individual, (b) any potential conflict of interest for each individual, and (c) for the panel as a whole, a balance of scientific findings, views, and biases. Note that this is similar to the balancing used by the National Academies' National Research Council.

EPA will hold a consultation with the contractor to review the membership of the proposed final panel, and as appropriate, the particular the information on the conflict of interest form, previous statements of views, etc. to address issues raised regarding proposed finalists. EPA will provide to the Contractor any recommendations that may be called for based on this review. The Contractor will then designate the final peer review panel, make formal arrangements with the members for their services, etc.

EPA will again post in the Federal Register the subject, date, time and weblink/call-in number of the peer review panel meeting at least 3 weeks before the panel meeting, along with the names of the peer review panel members and an invitation for the public to observe/listen to the panel meeting and orally comment, if desired. This notice will also include the following language: "EPA requests that no individual or organization contact in any way the panel members regarding the subject of the peer review meeting, send them written materials regarding the subject of the meeting, or make any offers or requests to any of them that appear to be linked to their participation in the peer review. EPA will ask panel members to report any such contacts, and will EPA take appropriate action to ensure the independence and impartiality of the peer review."

The Federal Register announcement will also provide information about the registration procedure to be conducted by the contractor and teleconference call/we blinks information. The contractor shall prepare a copy or provide a web link of the public comments from the EPA's electronic docket ([www.regulations.gov](http://www.regulations.gov)) after the close of the public comment period for distribution to the reviewers and the EPA WAM at least 30 days prior to the date of the meeting. The contractor will also provide a copy of the public comments sorted by charge question /topic area to the WAM and the peer reviewers. Reviewers will be instructed that the public comments

are for their consideration. The reviewers are not to respond to the individual comments necessarily, but may consider them as they feel appropriate.

Deliverable 2A: Charge to reviewers	Due: 2 weeks prior to publication of the FR notice
Deliverable 2B: Instructions to reviewers	Due: 2 weeks prior to publication of the FR notice
Deliverable 2C: Review materials (instruction to reviewers, Draft Risk Assessment, charge to reviewers, and supporting materials) sent to reviewers upon publication of the FR notice announcing the peer review meeting date. This should be available to the panel 30 days prior to the kick off meeting.	
Deliverable 2D: Pre-meeting reviewer comments	Due: 10 days before the peer review panel meeting teleconference
Deliverable 2E: Web link or copy of public comments	Due: upon close of the public comment period
Deliverable 2F: Web link and/or copy of proposed expert peer reviewers	Due: 30 days after close of the public comment period

D. Task 3 - Peer Review Panel Meetings and Logistics for Antimony Trioxide (CASRN 1309-64-4), HHCB (CASRN 1222-05-5), and Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4).

The contractor shall convene a kick off call to review the charge questions and scope of the assessment. This teleconference will allow peer reviewers to ask questions and clarifications of the Agency on charge and scope of assessments.

The contractor shall establish teleconferencing and web tools to allow remote access of peer review panels members and the public (approximately 100 participants).

This will be followed by full day peer review teleconference/weblink panel meeting for the reviewers to discuss the draft risk assessment. This panel meeting shall be scheduled at least 30 days after the close of the public comment period. The contractor shall facilitate the panel with the intent of promoting a discussion of the major issues identified by the reviewers. The contractor shall indicate to the panel that EPA is seeking the individual opinions of the reviewers and not a consensus of the group. The contractor shall indicate at the beginning of the meeting that the pre-meeting reviewer comments are available at the registration table. The contractor shall introduce the Chemical Manager (or representative), and the WAM, as the EPA point of contact for the meeting. The contractor shall indicate that the WAM (or the WAM's representative) is present during the panel meeting for the purpose of providing occasional clarification at the request of either the contractor or the reviewers. The contractor shall instruct the review panel chair to not engage the WAM in the discussion (except for limited clarification) or provide any opportunity for EPA to bias the reviewers' discussion. This shall be made clear at the outset of the panel meeting.

At the beginning of the meeting, the contractor shall inform observers that any comments or requests should be directed to the EPA point of contact (the WAM or the WAM's representative) and not to panel members or to the contractor. Observers should be informed that they are present only to listen and should not offer comments during the panel discussions. At no time during the meeting or breaks should observers attempt to discuss the assessment under review with any panel member. Panel members are asked to report any contact or attempt to influence the review during the meeting to the contractor. Observers who have pre-registered to make comments will be given an opportunity to speak briefly as specified in the Federal Register Notice announcing the meeting.

The contractor shall prepare the meeting agenda in consultation with the Panel Chair and provide a draft agenda

to the WAM for approval. A draft agenda shall be provided to the WAM 2 weeks prior to the meeting and the final agenda one week prior to the meeting.

The Panel Chair, in consultation with the contractor, shall prepare the agenda for the spring, 2013 (tentative) meeting. The agenda shall be submitted by the contractor to the EPA WAM for approval, at least 2 weeks in advance of the meeting. The Panel Chair shall facilitate the panel with the intent of promoting a discussion of the major issues identified by the reviewers. He/she shall provide an oral summary of the meeting at the end of the day's discussion with no attempt at resolution of issues (i.e., no attempt to achieve consensus or solicitation of a vote on any issue). The Panel Chair shall not ask for further comment from the EPA WAM or any interested public parties in attendance at the end of the day's discussion.

Other Expert Panelists - The other panelists (as well as the Panel Chair) shall review the charge and draft documents and submit his/her comments to the contractor in electronic format at least 10 days before the panel meeting as described in Task 3. The panelists should review the comments from the other reviewers to facilitate their participation in discussions at the teleconference/web conference peer review meeting. The contractor shall be responsible for arranging appropriate meeting teleconferencing and web tools to facilitate the panel meeting participation at remote sites. Audiovisual equipment, including a laptop computer and projector, and any other equipment needed to conduct the meeting shall be the responsibility of the contractor.

The contractor shall establish a mechanism for the public, and other interested parties, to register for the meeting. The registration process may be by phone, fax, mail, email and/or online. If a website is used for this purpose, the EPA WAM must approve the website prior to its activation. The website shall be activated on the day the Federal Register Notice is published. The public and other interested parties may register with the option to comment briefly at the meeting. The public and interested parties will be given up to 5 minutes each to make a statement at the beginning of the meeting prior to the panel's discussion of the assessment. No time will be allowed at the conclusion of the meeting for public comment.

The contractor shall prepare and distribute conference packets to all participants and registered observers (via web download). The packets should include at a minimum: meeting agenda, charge to the panel, a list of pre-registered participants, a list of panel reviewers and their affiliation, and a copy of the pre-meeting comments of the external peer review panel members. All materials should be of professional quality and appearance. New web/teleconference registrants shall sign in and that list shall be provided to the EPA WAM after the meeting. This latter information shall be provided to the WAM after the meeting.

Deliverable 3A: Meeting Agenda	Due: Draft Two weeks prior to the meeting; Final One week prior to the meeting
Deliverable 3B: Establish a website for the public and other interested parties to register for the meeting; the website shall be activated on the day that the Federal Register notice is published. Due Date: Publish date of FR Notice	
Deliverable 3C: Prepare Conference Packets	Due: Day of meeting

E. Task 4 - Final Post-Meeting Reviewer Comments for Antimony Trioxide (CASRN 1309-64-4), HHCB (CASRN 1222-05-5), and Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4).

The contractor shall receive and compile reviewers' final, post-meeting, edited comments in a final document. The reviewers shall have 2 weeks after the panel meeting to complete their edits. The contractor shall review



the comments to ensure that the reviewers have fulfilled their responsibilities under their agreement with the contractor. The contractor is not to edit nor rearrange comments, but provide them in a bound document, as they are sent in the original form with reviewers' cover/comment letter. The contractor may format the comments for consistency.

One electronic copy (MS Word 2003 or higher) of the compiled comments will be provided to the EPA WAM within 1 week of receipt of the reviewer comments for approval. Once approval is received, the contractor will produce a final electronic copy (MS Word 2003 or higher) and provide it via e-mail to the EPA WAM within 1 week of approval.

Deliverable 4: Final version of the reviewers' comments (one electronic copy) and compiled cover letters	Due: Within three weeks of receipt of the reviewers' final comments
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F) Task 5 - 30-Day Review of EPA's Disposition of Peer Reviewer Comments (**OPTIONAL**)

Within 90-120 days of the peer review meeting, the EPA will provide to the contractor a disposition of peer reviewer and public comments and the revised Draft Risk Assessment. The contractor shall distribute the revised Draft Risk Assessment to the peer reviewers, with a request for their comments within 30 days. The contractor shall forward any comments from the peer reviewers to the EPA WAM as they are received. Electronic copies of all deliverables shall be sent to the WAM and the PO.

**IV. MISCELLANEOUS - Software Application Files and Accessibility**

Software Application files if delivered to the Government shall be Microsoft Word, 7.0 or higher. All software and electronic information technology shall conform to the requirements relating to accessibility as detailed to the 1998 amendments to the Rehabilitation Act, particularly, but not limited to, §1194.21 Software applications and operating systems and § 1194.22 Web-based intranet and internet information and applications. See: <http://www.section508.gov/>

**Quality Assurance Requirements**

All written work products will adhere to EPA quality assurance/quality control guidelines, including the need for review of secondary data. Where the analysis and conclusions of the documents are based on specific secondary data and literature citations, the contractor will assure to the extent reasonably possible that the primary data was collected and analyzed following appropriate QA/QC procedures. Further, the EPA author of the documents will verify the quality of the data that is ultimately incorporated into the documents, and adhere to the requirements of the attached Quality Assurance form for the use of secondary data.

(The contractor and subcontractors are not permitted to disclose or discuss this PWS with anyone other than the assigned Contracting Officer and Contracting Officer Representatives)

**V. EPA CONTACT INFORMATION**

**Work Assignment Manager (WAM):**

**David Brooks**

Phone: 202-564-8603

Fax: 202-564-9063

Brooks.david@epa.gov

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1200 Pennsylvania Ave. NW

U. S. Environmental Protection Agency, 20006

Overnight Shipping Address (FedEx/UPS):

US EPA- OPPT\_RAD,

6th floor EPA EAST

1201 Constitution Avenue

Washington, DC 20004-3302

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**

Work Assignment Number

4-66

☐ Other ☐ Amendment Number:Contract Number  
EP-C-08-010

Contract Period 12/16/2008 To 11/30/2013

Title of Work Assignment/SF Site Name

Base Option Period Number 4

WA 4-66 External Peer Review

Contractor

SCIENTIFIC CONSULTING GROUP, INC, THE

Specify Section and paragraph of Contract SOW

2.2, 2.3

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 12/01/2012 To 11/30/2013

Comments:



Superfund

## Accounting and Appropriations Data



Non-Superfund

SFO  
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:

12/16/2008 To 11/30/2013

Cost/Fee:

LOE:

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name David Brooks

Branch/Mail Code:

Phone Number 202-564-8603

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 703-347-8523

FAX Number: 703-347-8696

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name William Yates

Branch/Mail Code:

Phone Number: 513-487-2055

FAX Number:

(Signature)

(Date)



## PERFORMANCE WORK STATEMENT

Contract Number: EP-C-08-010

Work Assignment Number 04-66

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**Title:** Title: External External Peer Review of the following draft risk assessments: Antimony Trioxide (CASRN 1309-64-4), HHCB (CASRN 1222-05-5), Trichloroethylene (CASRN 79-01-6), Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4).

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**SOW Section & Paragraph:** 2.2, 2.3

**PERIOD OF PERFORMANCE:** Option Year 4: Issuance to November 30, 2013

### I. Background

As part of EPA's continuing comprehensive approach to enhance the Agency's existing chemicals management program, in March 2012, EPA identified a work plan of 83 chemicals for further assessment under the Toxic Substances Control Act (TSCA). EPA identified seven of these chemicals for risk assessment in 2012. EPA intends to use the TSCA Work Plan Chemicals to help focus and direct the activities of the Existing Chemicals Program over the next several years. The documents to be reviewed consist of a Risk Assessment (approximately 100 pages in length plus 150 pages of references and appendices).

### II. OBJECTIVE

The U.S. EPA's Office of Pollution Prevention and Toxics (OPPT) has a requirement for external peer reviews of four documents: 1) Antimony Trioxide (CASRN 1309-64-4); 2) HHCB (CASRN 1222-05-5); 3) Trichloroethylene (CASRN 79-01-6); and 4) Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4), that the accuracy, content, and interpretation of findings be factual and scientifically sound. The review shall generate comments from the individual expert reviewers.

### III. DESCRIPTION OF TASKS

The contractor shall conduct the following tasks to accomplish the objective of this project: a) identify and select peer reviewers with appropriate expertise and determine absence of conflict of interest; b) provide the charge and review package contents to the reviewers; c) establish schedules and coordinate logistics for the letter peer review; and d) receive and compile written peer reviewer comments.

All work to be done under this work assignment shall be in compliance with the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006).

The documents to be reviewed consist of a Risk Assessment (approximately 100 pages in length plus 150 pages of references and appendices).

#### A) Task 1 - Establish Communication

The contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate (contractor) staff to clarify outstanding questions and confirm the schedule and specific tasks.

The contractor shall provide verbal status updates to the WAM on a weekly basis. The contractor shall initiate additional communication with the WAM should developments arise that could affect the conduct or schedule of this peer review.

Deliverable 1: Conference Call      Due: Three days after award of WA

#### B) Task 2 - Identify Scientific and Technical Experts

EPA is soliciting nominations of expert peer reviewers via a FRN from the public and submission of names with contact information (full name, address, affiliation, phone and e-mail) should be made within 30 days of the opening of this public comment period. The nominations of expert peer reviewers from the public will be relayed to the independent peer review contractor setting up the individual peer review panels.

Antimony Trioxide (CASRN 1309-64-4): The contractor shall independently identify a pool of 14 potential reviewers from which the contractor shall select and secure arrangements with 7 reviewers who are experts in the following areas: exposure modeling expert, aquatic ecotoxicology, terrestrial ecotoxicology, and inorganic chemist addressing water and sediment issues, and ground water. Experts shall be chosen by the contractor to participate in the external peer review panel. While contractor shall choose experts based upon scientific expertise, the contractor is encouraged to consider experts with diverse backgrounds that represent a range of employment sectors.

HHCB (CASRN 1222-05-5): The contractor shall independently identify a pool of 14 potential reviewers from which the contractor shall select and secure arrangements with 7 reviewers who are experts in the following areas: aquatic ecotoxicology, terrestrial ecotoxicology, fate and biodegradation, fate and bioaccumulation, environmental risk assessment (aquatic and terrestrial), analytical chemistry of organic waste water contaminants and human health risk assessment. Experts shall be chosen by the contractor to participate in the external peer review panel. While contractor shall choose experts based upon scientific expertise, the contractor is encouraged to consider experts with diverse backgrounds that represent a range of employment sectors.

Trichloroethylene (CASRN 79-01-6): The contractor shall independently identify a pool of 14 potential reviewers from which the contractor shall select and secure arrangements with 9 reviewers who are experts in the following areas: toxicology of TCE (developmental cardiotoxicity, immunotoxicology, reproductive toxicology, and cancer biology, expertise in PBPK modeling for TCE, exposure of volatile organics, experts on use of volatiles as solvent degreasers and in the arts/crafts field, chemical/environmental risk assessment experts, experts familiar with environmental release data (i.e., TRI, NEI) and associated modeling/interpretation. Experts shall be chosen by the contractor to participate in the external peer review panel. While contractor shall choose experts based upon scientific expertise, the contractor is encouraged to consider experts with diverse backgrounds that represent a range of employment sectors.

Methylene Chloride (CASRN 75-09-2) and N-Methylpyrrolidone (CASRN 872-50-4): The contractor shall independently identify a pool of 14 potential reviewers from which the contractor shall select and secure arrangements with up to 9 reviewers who are experts in the following areas: inhalation toxicology, toxicokinetics/PBPK modeling, dermal toxicology, neurotoxicology, immunotoxicology, developmental and reproductive toxicology, cancer biology, expertise in US consumer modeling (inhalation and dermal), expertise in occupational exposure assessment (inhalation and dermal) especially as related to VOCs. Experts shall be chosen by the contractor to participate in the external peer review panel. While contractor shall choose experts based upon scientific expertise, the contractor is encouraged to consider experts with diverse backgrounds that represent a range of employment sectors.

The contractor shall certify in writing to the WAM that the selected reviewers are free from any conflict of interest or an appearance of a lack of impartiality as follows:

1. Within 1 week of the initial conference call (via letter to EPA, see template for the selection of peer reviewers' letter);
2. Two weeks before the meeting (notice of recertification); and
3. The day of the meeting (notice of recertification).

The contractor shall instruct peer reviewers to report any changes that would impact their COI or impartiality status anytime during the process. The contractor shall immediately notify the CO, the PO and WAM of any changes.

All of the reviewers shall also have broad expertise in the area of toxicology, and understanding of EPA risk assessment guidance. The reviewers shall have scientific credentials equivalent to a Ph.D. or M.D. and shall be regarded as experts in their field. Expertise shall be judged by authorship on original publications and/or reviews in peer-reviewed scientific journals. Reviewers may also be judged by other measures of expertise including professional accomplishments and recognition by professional societies.

The contractor shall provide the WAM with the affiliation, qualifications, and curriculum vitae for each of the 14 candidate reviewers. The contractor shall ensure that the candidate reviewers meet the technical selection criteria and determine any actual or potential conflict of interest where it exists. Contractor will ask the potentially qualified candidates if they are interested and available for the date(s) of the peer review meeting(s). From each person that is interested and available, the Contractor will obtain: (a) a current, complete resume, (b) a completed conflict of interest form containing the information specified by EPA, and (c) if not on the resume, a list of pertinent publications during the past 5 years, with identification of the funding source(s) for the work presented in each publication. The Contractor will supplement the information from candidates by Internet searches and other methods that are appropriate. If EPA determines that the reviewers are scientifically unqualified for the specific review, the contractor shall have five days to submit substitutes for review. The WAM can provide comments to the contractor regarding the expertise and potential conflicts of interest of the proposed reviewers. The final selection of reviewers will be the responsibility of the contractor. The contractor shall designate one of the reviewers as the Panel Chair with the approval of the WAM. This individual shall have demonstrated abilities for leading a scientific group and shall have a working knowledge of EPA risk assessment practices.

The contractor shall contact the approved candidates and arrange for their participation in the review and attend 3 conference/web conferences calls, tentatively scheduled to begin spring 2013. Review materials will include the charge to the reviewers and a Draft External Peer review Draft Risk Assessment with electronic copies of references cited and/or access to the health & Environmental Research Online (HERO) database <http://hero.epa.gov/> (all provided by the EPA WAM). A draft charge will be provided to the contractor containing questions identified by the Agency. These charge questions must be included in the final charge. The contractor may add questions or suggest revisions to the charge provided by EPA. The charge must be consistent with the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006).

Deliverable 2. The Contractor shall provide a COI certification letter of the decision that includes a list of (14) prospective reviewers within 1 week of the initial conference call. The letter shall certify that either no COI or appearance of a lack of impartiality exists or such has been resolved for each prospective reviewer.

Deliverable 2A: CVs for the peer reviewers      Due: Two weeks after WA award  
expert panel selection      Due: Three weeks after WA award

### C. Task 3 -- Pre-Meeting Review Period and Comments

The contractor shall draft instructions to the reviewers in accordance with the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006). The instructions shall inform the reviewers that their pre-meeting and post-meeting written comments will be made publicly available via distribution at the peer review meeting and the OPPT web site via links to the e-docket, respectively. The instructions shall also inform reviewers that from the time they accept the invitation to review the assessment; they should have no communications with members of the public, EPA, or other federal agencies on the assessment under review. Reviewers shall be instructed that if they are contacted in person or in writing on the assessment by anyone other than the contractor or another panel member, they should immediately inform the contractor. The contractor shall immediately inform the PO and WAM of any reports by panel members of pre-meeting contacts regarding the assessment under review.

The contractor shall provide and send to each reviewer the Draft Workplan Risk Assessment, the charge to the reviewers, and instructions for the peer review according to the EPA Science Policy Council Handbook: Peer Review (Third Edition, EPA 100-B-06-002, 2006).

The contractor shall manage and monitor the review process and deliverable due dates. The reviewers will be allowed 6 weeks to complete their initial review. The contractor shall receive and compile reviewers' comments in a draft pre-meeting document. The contractor shall review the comments to ensure that the reviewers have fulfilled their responsibilities under their agreement with the contractor. The contractor is not to edit nor rearrange comments, but provide them in an electronic format (MS Word 2007 format or higher), as they are sent in the original form with reviewers' cover/comment letter. The compiled comments shall be provided to the WAM at least 10 days before the peer review panel meeting. An electronic copy of the draft final pre-meeting document shall be provided to each reviewer at least 10 days before the peer review panel meeting.

At least 90 days prior to the date of the first meeting, EPA will announce in the Federal Register: (a) the availability of the assessment to the public, including a request for public comment (60 day public comment period);

At least 60 days prior to the first meeting The Contractor will select a proposed final review panel based on: (a) expertise, knowledge and experience of each individual, (b) any potential conflict of interest for each individual, and (c) for the panel as a whole, a balance of scientific findings, views, and biases. Note that this is similar to the balancing used by the National Academies' National Research Council.

EPA will hold a consultation with the contractor to review the membership of the proposed final panel, and as appropriate, the particular the information on the conflict of interest form, previous statements of views, etc. to address issues raised regarding proposed finalists. EPA will provide to the Contractor any recommendations that may be called for based on this review. The Contractor will then designate the final peer review panel, make formal arrangements with the members for their services, etc.

EPA will again post in the Federal Register the subject, date, time and weblink/call-in number of the peer review panel meeting at least 3 weeks before the panel meeting, along with the names of the peer review panel members and an invitation for the public to observe/listen to the panel meeting and orally comment, if desired. This notice will also include the following language: "EPA requests that no individual or organization contact in



any way the panel members regarding the subject of the peer review meeting, send them written materials regarding the subject of the meeting, or make any offers or requests to any of them that appear to be linked to their participation in the peer review. EPA will ask panel members to report any such contacts, and will EPA take appropriate action to ensure the independence and impartiality of the peer review.”

The Federal Register announcement will also provide information about the registration procedure to be conducted by the contractor and teleconference call/we blinks information. The contractor shall prepare a copy or provide a web link of the public comments from the EPA’s electronic docket ([www.regulations.gov](http://www.regulations.gov)) after the close of the public comment period for distribution to the reviewers and the EPA WAM at least 30 days prior to the date of the meeting. The contractor will also provide a copy of the public comments sorted by charge question /topic area to the WAM and the peer reviewers. Reviewers will be instructed that the public comments are for their consideration. The reviewers are not to respond to the individual comments necessarily, but may consider them as they feel appropriate.

Deliverable 3A: Charge to reviewers	Due: 2 weeks prior to publication of the FR notice
Deliverable 3B: Instructions to reviewers	Due: 2 weeks prior to publication of the FR notice
Deliverable 3C: Review materials (instruction to reviewers, Draft Risk Assessment, charge to reviewers, and supporting materials) sent to reviewers upon publication of the FR notice announcing the peer review meeting date. This should be available to the panel 30 days prior to the kick off meeting.	
Deliverable 3D: Pre-meeting reviewer comments	Due: 10 days before the peer review panel meeting teleconference
Deliverable 3E: Web link or copy of public comments	Due: upon close of the public comment period
Deliverable 3F: Web link and/or copy of proposed expert peer reviewers	Due: 30 days after close of the public comment period

#### D. Task 4 - Peer Review Panel Meetings and Logistics

The contractor shall convene a kick off call to review the charge questions and scope of the assessment. This teleconference will allow peer reviewers to ask questions and clarifications of the Agency on charge and scope of assessments.

The contractor shall establish teleconferencing and web tools to allow remote access of peer review panels members and the public (approximately 100 participants).

This will be followed by full day peer review teleconference/weblink panel meeting for the reviewers to discuss the draft risk assessment. This panel meeting shall be scheduled at least 30 days after the close of the public comment period. The contractor shall facilitate the panel with the intent of promoting a discussion of the major issues identified by the reviewers. The contractor shall indicate to the panel that EPA is seeking the individual opinions of the reviewers and not a consensus of the group. The contractor shall indicate at the beginning of the meeting that the pre-meeting reviewer comments are available at the registration table. The contractor shall introduce the Chemical Manager (or representative), and the WAM, as the EPA point of contact for the meeting. The contractor shall indicate that the WAM (or the WAM’s representative) is present during the panel meeting for the purpose of providing occasional clarification at the request of either the contractor or the reviewers. The contractor shall instruct the review panel chair to not engage the WAM in the discussion (except for limited clarification) or provide any opportunity for EPA to bias the reviewers’ discussion. This shall be made clear at the outset of the panel meeting.

At the beginning of the meeting, the contractor shall inform observers that any comments or requests should be directed to the EPA point of contact (the WAM or the WAM's representative) and not to panel members or to the contractor. Observers should be informed that they are present only to listen and should not offer comments during the panel discussions. At no time during the meeting or breaks should observers attempt to discuss the assessment under review with any panel member. Panel members are asked to report any contact or attempt to influence the review during the meeting to the contractor. Observers who have pre-registered to make comments will be given an opportunity to speak briefly as specified in the Federal Register Notice announcing the meeting.

The contractor shall prepare the meeting agenda in consultation with the Panel Chair and provide a draft agenda to the WAM for approval. A draft agenda shall be provided to the WAM 2 weeks prior to the meeting and the final agenda one week prior to the meeting.

The Panel Chair, in consultation with the contractor, shall prepare the agenda for the spring, 2013 (tentative) meeting. The agenda shall be submitted by the contractor to the EPA WAM for approval, at least 2 weeks in advance of the meeting. The Panel Chair shall facilitate the panel with the intent of promoting a discussion of the major issues identified by the reviewers. He/she shall provide an oral summary of the meeting at the end of the day's discussion with no attempt at resolution of issues (i.e., no attempt to achieve consensus or solicitation of a vote on any issue). The Panel Chair shall not ask for further comment from the EPA WAM or any interested public parties in attendance at the end of the day's discussion.

**Other Expert Panelists** - The other panelists (as well as the Panel Chair) shall review the charge and draft documents and submit his/her comments to the contractor in electronic format at least 10 days before the panel meeting as described in Task 3. The panelists should review the comments from the other reviewers to facilitate their participation in discussions at the teleconference/web conference peer review meeting. The contractor shall be responsible for arranging appropriate meeting teleconferencing and web tools to facilitate the panel meeting participation at remote sites. Audiovisual equipment, including a laptop computer and projector, and any other equipment needed to conduct the meeting shall be the responsibility of the contractor.

The contractor shall establish a mechanism for the public, and other interested parties, to register for the meeting. The registration process may be by phone, fax, mail, email and/or online. If a website is used for this purpose, the EPA WAM must approve the website prior to its activation. The website shall be activated on the day the Federal Register Notice is published. The public and other interested parties may register with the option to comment briefly at the meeting. The public and interested parties will be given up to 5 minutes each to make a statement at the beginning of the meeting prior to the panel's discussion of the assessment. No time will be allowed at the conclusion of the meeting for public comment.

The contractor shall prepare and distribute conference packets to all participants and registered observers (via web download). The packets should include at a minimum: meeting agenda, charge to the panel, a list of pre-registered participants, a list of panel reviewers and their affiliation, and a copy of the pre-meeting comments of the external peer review panel members. All materials should be of professional quality and appearance. New web/teleconference registrants shall sign in and that list shall be provided to the EPA WAM after the meeting. This latter information shall be provided to the WAM after the meeting.

Deliverable 4A: Meeting Agenda	Due: Draft Two weeks prior to the meeting; Final One week prior to the meeting
Deliverable 4B: Establish a website for the public and other interested parties to register for the meeting; the	

website shall be activated on the day that the Federal Register notice is published. Due Date: Publish date of FR Notice

Deliverable 4C: Prepare Conference Packets

Due: Day of meeting

#### E. Task 5 - Final Post-Meeting Reviewer Comments

The contractor shall receive and compile reviewers' final, post-meeting, edited comments in a final document. The reviewers shall have 2 weeks after the panel meeting to complete their edits. The contractor shall review the comments to ensure that the reviewers have fulfilled their responsibilities under their agreement with the contractor. The contractor is not to edit nor rearrange comments, but provide them in a bound document, as they are sent in the original form with reviewers' cover/comment letter. The contractor may format the comments for consistency.

One electronic copy (MS Word 2003 or higher) of the compiled comments will be provided to the EPA WAM within 1 week of receipt of the reviewer comments for approval. Once approval is received, the contractor will produce a final electronic copy (MS Word 2003 or higher) and provide it via e-mail to the EPA WAM within 1 week of approval.

Deliverable 5: Final version of the reviewers' comments (one electronic copy) and compiled cover letters

Due: Within three weeks of receipt of the reviewers' final comments

#### F) Task 6 - 30-Day Review of EPA's Disposition of Peer Reviewer Comments (**OPTIONAL**)

Within 90-120 days of the peer review meeting, the EPA will provide to the contractor a disposition of peer reviewer and public comments and the revised Draft Risk Assessment. The contractor shall distribute the revised Draft Risk Assessment to the peer reviewers, with a request for their comments within 30 days. The contractor shall forward any comments from the peer reviewers to the EPA WAM as they are received. Electronic copies of all deliverables shall be sent to the WAM and the PO.

#### IV. MISCELLANEOUS - Software Application Files and Accessibility

Software Application files if delivered to the Government shall be Microsoft Word, 7.0 or higher. All software and electronic information technology shall conform to the requirements relating to accessibility as detailed to the 1998 amendments to the Rehabilitation Act, particularly, but not limited to, §1194.21 Software applications and operating systems and § 1194.22 Web-based intranet and internet information and applications. See: <http://www.section508.gov/>

#### Quality Assurance Requirements

All written work products will adhere to EPA quality assurance/quality control guidelines, including the need for review of secondary data. Where the analysis and conclusions of the documents are based on specific secondary data and literature citations, the contractor will assure to the extent reasonably possible that the primary data was collected and analyzed following appropriate QA/QC procedures. Further, the EPA author of the documents will verify the quality of the data that is ultimately incorporated into the documents, and adhere to the requirements of the attached Quality Assurance form for the use of secondary data.

(The contractor and subcontractors are not permitted to disclose or discuss this PWS with anyone other than the assigned Contracting Officer and Contracting Officer Representatives)

## **V. EPA CONTACT INFORMATION**

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